JUN 1 3 2013

510(k) Summary
Quantum BioEngineering, Ltd.
Quantum™ Dental Implant System
K130787

May 20, 2013

ADMINISTRATIVE INFORMATION

Manufacturer Name	Quantum BioEngineering, Ltd. 201 N. University Drive, Suite 101 Plantation, FL 33324 Telephone: +1 (954) 474-4707 Fax: +1 (954) 474-2533
Official Contact	Raul R. Mena, D.M.D., President
Representative/Consultant	Linda K. Schulz Floyd G. Larson PaxMed International, LLC 12264 El Camino Real, Suite 400 San Diego, CA 92130 Telephone: +1 (858) 792-1235 Fax: +1 (858) 792-1236 Email: lschulz@paxmed.com flarson@paxmed.com

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name	Quantum™ Dental Implant System
Common Name	Dental Implant
Classification Name	Implant, endosseous, root form
Classification Regulations	Class II, 21 CFR 872.3640
Product Code	DZE
Classification Panel	Dental Products Panel
Reviewing Branch	Dental Devices Branch

INTENDED USE

Quantum™ Dental Implant System implants are intended for immediate or delayed placement in the bone of the maxillary or mandibular arch for use as support for crowns, bridges or overdentures. When a one-stage surgical approach is applied, threaded implants may be immediately loaded when good primary stability is achieved and the functional load is appropriate. Delayed loading is required when using the push-in technique for fin-type or threaded implants. The Ø3.0 mm Quantum Dental Implant is limited to replacement of maxillary lateral incisors and mandibular central and lateral incisors.

DEVICE DESCRIPTION

The Quantum Dental Implant System implants included in this submission are root form, endosseous dental implants with a Morse taper and external hex abutment interface. They are made of titanium alloy, with three surface options. Implants are provided in both a threaded and a grooved (fin-type) design. The implants are 3.0 mm in diameter and are available in four lengths (8, 9, 11, & 14 mm)

EQUIVALENCE TO MARKETED DEVICE

The Quantum Dental Implant System is substantially equivalent in indications and design principles to the following predicate devices, each of which has been determined by FDA to be substantially equivalent to pre-amendment devices:

K112279 - Quantum BioEngineering, Ltd., Quantum™ Dental Implant System
K002241 - Quantum BioEngineering, Ltd., Quantum™ Versatility Dental Implant System
K991250 - Quantum BioEngineering, Ltd., Quantum Versatility™ Implant System
K101849 - Bicon, LLC, Bicon Dental Implant System 3.0mm
K101732 - Astra Tech AB, Astra Tech Implant System

The subject device and the predicate devices have the same intended use and have the same technological characteristics. The subject device and the predicate devices encompass the same range of physical dimensions and characteristics, including implant diameter, length, and surface treatment. Any differences in the technological characteristics between the subject device and the predicate devices do not raise new issues of safety or efficacy.

Performance testing is provided to demonstrate substantial equivalence and includes static and dynamic compression-bending testing according to ISO 14801. The data included in this submission demonstrates substantial equivalence to the predicate devices listed above.

Overall, the Quantum Dental Implant System has the following similarities to the predicate devices:

- has the same intended use,
- uses the same operating principle,
- incorporates the same basic design,
- incorporates the same or very similar materials, and
- has similar packaging and is sterilized using the same materials and processes.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 13, 2013

Quantum BioEngineering, Limited
C/O Ms. Linda Schulz
PaxMed International, Limited Liability Company
12264 El Camino Real, Suite 400
SAN DIEGO CA 92130

Re: K130787
Trade/Device Name: Quantum™ Dental Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: May 20, 2013
Received: May 21, 2013

Dear Ms. Schulz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Susan Runner DDS MA Mary S. Runner -S

Kwame Ulmer, M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K130787

Device Name: Quantum™ Dental Implant System

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Andrew I. Steen -S
2013.06.07 14:45:16 -04'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K130787